

The Office Action of October 3, 2002 has been reviewed and its contents carefully noted. Reconsideration of this case is earnestly requested. Claims 1-15 remain in this case, new claim 15 being added by this response. New claim 15 is supported generally throughout the application; no new matter has been added.

**The Restriction Requirement**

The Examiner has made a Restriction Requirement and has identified four Groups of claims, as follows:

Group I - claims 1-7, 13 and 14, drawn to plants comprising a polynucleotide encoding a human acetylcholinesterase, classified in Class 800, subclass 295.

Group II - claims 8 and 9, drawn to methods of making a plant expressing human acetylcholinesterase, classified in Class 435, subclass 69.1.

Group III - claim 10, drawn to a method of using a plant expressing human acetylcholinesterase, classified in Class 800, subclass 278.

Group IV - claims 11 and 12, drawn to isolated polynucleotides comprising a nucleic acid of SEQ ID NO: 1 through SEQ ID NO: 5, classified in Class 536, subclass 23.1.

The election of Group I and the species defined by claims 1-7, 13 and 14 is hereby confirmed. However, the requirement for restriction, as best understood, is respectfully traversed.

The MPEP states the following with regard to stating a *prima facie* case of restriction between patentably distinct inventions:

"There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

#### GUIDELINES

Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the restriction requirement in most cases.

Where plural inventions are capable of being viewed as related in two ways, both applicable criteria for distinctness must be demonstrated to support a restriction requirement.

If there is an express admission that the claimed inventions are obvious over each other within the meaning of 35 U.S.C. 103, restriction should not be required. *In re Lee*, 199 USPQ 108 (Comm'r Pat. 1978).

For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria is set forth in MPEP § 803.02. Insofar as the criteria for restriction or election practice relating to claims to genus-species, see MPEP § 806.04(a) - § 806.04(i) and § 808.01(a)".

The Examiner states that inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be used as biomass, for energy production. It is respectfully submitted that such fact is irrelevant. Even if it were true, that fact does not address issues (1) or (2) above. More particularly, even if the product can be used as biomass for energy production, that does not show that (1) that the process as claimed can be used to make other and materially different product (*i.e.*, it is still the same product, not a materially different product) or (2) that the product as claimed can be made by another and materially different process. Thus, it is

respectfully submitted that the Examiner has not made a *prima facie* restriction requirement in regard to Groups I and II.

The Examiner states that inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the Examiner asserts that the process for using the transgenic plant can also be used to produce acetylcholinesterase. It is respectfully submitted that such use of the transgenic plant (*i.e.*, to produce acetylcholinesterase) is not materially different from the claimed process of using the plant to express acetylcholinesterase for a particular use, as a therapeutic agent. More particularly, in the claimed process of use, the plant is indeed used to produce acetylcholinesterase, which subsequently is administered to a patient. If the Examiner envisions a different use for the expressed acetylcholinesterase, she has not identified that use. Thus, it is respectfully submitted that the Examiner has not made a *prima facie* restriction requirement in regard to Groups I and III.

The Examiner states that inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the Examiner asserts that the different inventions are transgenic plants, which are complex biological organisms, and nucleic acids, which are biochemical substances, and they have different modes of operation, different functions, or different effects. It is respectfully submitted that the Examiner has made a *prima facie* restriction requirement in regard to Groups I and IV because there is no showing that the claimed nucleic acids are not disclosed as capable of use together with the claimed transgenic plants. Indeed, it is clear from Applicant's disclosure that the claimed nucleic acids are capable of use together with the claimed transgenic plants. In fact, the claimed transgenic plants are claimed as being used with the claimed nucleic acids. Thus, it is respectfully submitted that the Examiner has not made a *prima facie* restriction requirement in regard to Groups I and IV.

The Examiner states that inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the Examiner asserts that they have different modes of operation, different functions, or different effects-the methods have different starting materials, use different steps, and produce different products. However, again, the Examiner has not shown that the inventions of Groups II and III are not disclosed as capable of use together. In fact, as in the immediately preceding paragraph, the inventions of Groups II and III are indeed disclosed as capable of use together. Thus, it is respectfully submitted that the Examiner has not made a *prima facie* restriction requirement in regard to Groups II and III.

The Examiner asserts that inventions IV and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the Examiner asserts that the product as claimed can be used in a materially different process of using that product, in that the polynucleotides can be used as templates for in vitro expression systems. It is respectfully submitted that use of the claimed polynucleotides as templates for in vitro expression does not differ materially from using the polynucleotides as templates for in vivo expression (*i.e.*, in plants); the examiner has merely identified a difference without a distinction, which clearly is not a materially different process. Thus, it is respectfully submitted that the Examiner has not made a *prima facie* restriction requirement in regard to Groups IV and III.

The Examiner states that inventions IV and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the Examiner asserts that the different inventions, DNA and methods of using a transgenic plant, cannot be used together and they are chemical substances compared to complex biochemical organisms. It is respectfully submitted that the claimed DNA molecules are indeed disclosed as being capable of being used together with the claimed transgenic plants. Indeed, the claimed transgenic plants include the claimed DNA molecules, which clearly

constitutes use together. Thus, it is respectfully submitted that the Examiner has not made a *prima facie* restriction requirement in regard to Groups IV and III.

Applicant respectfully requests that the restriction requirement be withdrawn. If the Examiner does not withdraw the restriction requirement, then Applicant requests that the Examiner state the restriction properly and in complete terms, so that Applicant may properly respond to the requirement. If the Examiner disagrees, or believes for any other reason that direct contact with Applicant's attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

Applicant believes the claims, as amended, are patentable over the prior art, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicant's attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

Respectfully Submitted:

By: Thomas T. Aquilla  
Thomas T. Aquilla, Reg. No. 43,473  
Attorney for Applicant

Brown & Michaels, PC  
400 M&T Bank Building - 118 North Tioga Street  
Ithaca, New York 14850  
(607) 256-2000 • (607) 256-2000 (fax)  
e-mail: aquilla@bpmlegal.com

Dated: October 25, 2002